4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Development of Animal Models of Pregnancy to Address Medical Countermeasures for Influenza in the "At Risk" Population of Pregnant Women: Influenza as a Case Study; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration's (FDA) Center for Drug Evaluation and Research and FDA's National Center for Toxicological Research are announcing a 2-day public workshop entitled "Development of Animal Models of Pregnancy to Address Medical Countermeasures for Influenza in the 'At Risk' Population of Pregnant Women: Influenza as a Case Study." The purpose of this workshop is to provide a forum to carefully consider scientific issues related to selecting animal models for use in evaluating medical influenza countermeasures (anti-influenza drugs) that may be given during pregnancy. Specifically, this workshop will address experimental design issues in selecting the most appropriate animal model that mimics human pregnancy. The goal is to use this model to evaluate how pregnancy changes the pharmacokinetics of anti-influenza drugs in animals and compare those changes to the changes that are known to occur in human pregnancy. The data obtained from using this model may enhance the knowledge base needed to extrapolate the effects of pregnancy on other medical countermeasures.

Date and Time: The public workshop will be held on April 30, 2012, from 8:30 a.m. to 5 p.m., and on May 1, 2012, from 8:30 a.m. to 5 p.m.

Location: The public workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Central Shared Use (CSU) Bldg. 2, rm. 2047, Silver Spring, MD 20993-0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1, where routine security check procedures will be performed, a visitor badge will be issued, and an escort will be provided to the meeting room. Government-issued identification will be needed. For additional information on parking and security, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Contact Person: For questions about the workshop, please contact Cindy de Sales, cindy@tepgevents.com, 240-316-3207.

Registration: There is no fee to attend the public workshop, but attendees must register in advance. Space is limited, and registration will be on a first-come, first-served basis. Persons interested in attending this workshop must register online at http://fda.contractmeetings.com before April 16, 2012. Non-U.S. citizens are subject to additional security screening, and they should register as soon as possible. For those without Internet access, please contact Cindy de Sales (see Contact Person) to register. Onsite registration is not available.

If you need special accommodations due to a disability, please contact Cindy de Sales (see Contact Person) at least 7 days in advance.

SUPPLEMENTARY INFORMATION: During seasonal and pandemic influenza outbreaks, pregnant women generally have greater morbidity and mortality than other adults. The data from the 2009 H1N1 influenza pandemic suggested that pregnant women were at increased risk for

medical complications. There is limited information regarding the efficacy, pharmacokinetics, optimal dosing, and side effects of anti-influenza drugs that may need to be used during pregnancy. The same is true for most drugs to treat diseases due to other infectious agents.

The anti-influenza drugs have been selected for further study because the influenza virus can infect pregnant women, and oseltamivir, an anti-influenza drug of the neurominadase inhibitor class, was recommended for treatment of and/or for prophylaxis in pregnant women during the 2009 H1N1 influenza pandemic. In addition, two clinical studies conducted in pregnant women provide some pharmacokinetic data for oseltamivir.

This workshop is open to all interested parties. The target audience includes professionals in the scientific community interested in discussing the challenges of evaluating medical countermeasures for effective and safe use during pregnancy.

The workshop will include plenary and breakout sessions on the scientific challenges in the development of animal models of pregnancy that can be used to address the safety and efficacy of medical countermeasures. Broad topics to be covered in the plenary sessions include: (1) The physiology and pharmacology of pregnancy as it relates to model development; (2) the role of animal models in evaluating medical countermeasures, including influenza therapies, that may be used during pregnancy; and (3) experimental design considerations. Topics of the breakout sessions will include: (1) Animal model selection, (2) design of the pharmacokinetic studies, and (3) additional issues in experimental design.

Background information on the public workshop, registration information, the agenda, and other relevant information will be posted, as it becomes available, on the registration Web site at http://fda.contractmeetings.com.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. A transcript will also be available in either hard copy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Send faxed requests to 301-827-9267.

Dated: March 21, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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